

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: David W. JOHNSON *et al.* Confirmation No.: 1511
Serial No.: 10/698,424 Group Art Unit: 1638
Filed: November 3, 2003 Examiner: Keith O Neal Robinson
For: **ALFALFA PLANTS HAVING IMPROVED STANDABILITY AND/OR FAST RECOVERY AFTER HARVEST AND METHODS FOR PRODUCING SAME**

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PRE-APPEAL BRIEF REQUEST FOR REVIEW

In response to the Final Office Action ("Final Action") of March 31, 2008, Applicants respectfully request a review of the above-identified matter prior to filing of an Appeal Brief. A Notice of Appeal is filed herewith under 37 C.F.R. 41.31.

As discussed more fully below, Applicants believe that the Examiner has made clear errors in rejecting pending claims 2-4 and 6-19 under 35 U.S.C. § 112, first paragraph and 35 U.S.C. § 102/103.

Written Description Rejection.

Claims 2-4 and 6-19 stand rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement.

Applicants believe that the following paragraph summarizes the Examiner's position regarding this rejection:

"Applicant appears to claim any alfalfa plant having the claimed characteristics, even those that are made by other methods than those described in the specification. However, the specification only provides evidence that Applicant was in possession of alfalfa variety CS 75046 (see pages 25-29), CW 83201 (see pages 29-35), CW 85029 (see pages 35-39) and CW 95026 (see pages 40-45) and describes specific methods for producing such varieties. Therefore, it is unclear how Applicant can be in possession of alfalfa plants having the same characteristics but produced by different methods or produced using different parental materials." (Detailed Action, page 3, second full paragraph).

As an initial matter, Applicants note that they are not claiming a method or a product-by-process but rather a class of *Medicago sativa* alfalfa **varieties with 8% or greater faster recovery after spring**

green-up or after harvest coupled with having 15% or greater more erect stems at late bloom when compared to the best commercial check varieties available. Therefore, Applicants are not claiming just any *Medicago sativa* alfalfa plants as alleged by the Examiner, but rather are claiming *Medicago sativa* alfalfa varieties with specific and clearly defined traits hitherto unknown to those skilled in the art of alfalfa breeding.

Vas-Cath Inc. v. Mahurkar, which is relied upon by the Examiner to support this rejection, held that “to satisfy the written description requirement, an applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention, and that the invention, in that context, is whatever is now claimed.” *Id.*, 935 F.2d 1555, 1563-64, 19 USPQ2d 1111, 1117 (Fed. Cir. 1991). See, also, the U.S. Patent & Trademark Office’s (“US PTO”) position on the teachings of this case as provided at M.P.E.P. § 2163.02. As discussed supra and in great detail in the Amendment and Response Under 37 C.F.R. § 1.111, filed June 21, 2006, in response to the First Office Action, Applicants have clearly met the standard for the written description requirement set forth in *Vas-Cath Inc. v. Mahurkar*. The presently pending claims clearly set forth exactly how a potential infringer can determine whether a particular *Medicago sativa* alfalfa variety falls within the metes and bounds of the claimed invention, wherein the claimed elements of those metes and bounds are clearly and explicitly set forth in the as-filed specification.

The Examiner admits on-the-record that “the specification provides detailed descriptions of the development of four very diverse and distinct *Medicago sativa* alfalfa varieties derived from diverse genetic backgrounds” (Detailed Action, page 5, last paragraph, underlining added). Applicants maintain that anyone skilled in the art of alfalfa variety development can follow the procedures described in the as-filed specification to develop additional varieties which fall within the limitations of the claimed genus of alfalfa varieties with 8% or greater faster recovery after spring green-up or after harvest and 15% or greater more erect stems at late (i.e., 75% bloom) when compared to the specific adapted check alfalfa varieties as set forth in the claims. Alternatively, one skilled in the art can use any of Applicant’s inventive, disclosed and deposited alfalfa varieties to develop additional alfalfa varieties which meet the claimed limitations. Applicants believe that it is a clear error for the Examiner to maintain this rejection because the as-filed specification conveys the invention to the public with reasonable clarity, Applicants’ were clearly in possession of the invention at the time of filing, and that invention is now what is being claimed.

Enablement Description Rejection.

Claims 2-4 and 6-19 stand rejected under 35 U.S.C. § 112, first paragraph, “because the specification, while being enabling for alfalfa varieties CW 75046, CW 83201, CW 85029 and CW

95026, does not reasonably provide enablement for any and all alfalfa plants having the same characteristics" (Detailed Action, page 6, last paragraph).

As an initial matter, Applicants note that "[T]he examiner's analysis must consider all of the evidence related to each of these factors, and any conclusion of nonenablement must be based on the evidence as a whole" (MPEP 2164.01(a), citing *In re Wands* 858 F.2d 737, 740 8 USPQ2d at 1404, 1407). The Examiner's rejection does not meet this standard and we believe this is a clear error.

Applicants respectfully direct the panel's attention to the very detailed and complete analysis of each of the eight considerations in *In re Wands*, 858F 2d 731, 9 USPQ2d 1400 (Fed. Cir. 1988), as set forth at pages 14-19 of the Amendment and Response Under 37 C.F.R. § 1.111, filed June 21, 2006.

If the Examiner's extremely broad-stroked rejection is maintained, then there appears to be no way any inventor of a "genus" plant breeding invention can ever obtain claims to anything broader than a narrow "species" claim. Clearly, that is not the standard set by Congress, the courts or the US PTO and the Examiner has committed a clear error.

Alfalfa breeding is a predictable art where, like here, Applicants have provided a clear and detailed plant breeding roadmap to accomplishing the claimed invention. Surely, in view of Applicants' disclosure, the claimed invention is predictable and the Examiner's rejection is a clear error.

The specification clearly teaches that the instant claimed invention is an advancement in the art of breeding alfalfa for improved standability. See, for example, page 10, lines 18-20:

Prior to the instant invention, the standability differences between commercial alfalfa varieties has been so small that most alfalfa breeders do not even rate their varieties for this important trait.

The Examiner relies on Bouton as teaching that the "[collection and development of parents] is one of the most important decisions in the breeding program because the end product will only be as good as the parents which originally went into the process". Applicants agree and in the originally-filed specification provided a detailed description of the parental lines that went into forming each of the four diverse, exemplary alfalfa varieties of the presently claimed invention. See, for example, page 25, lines 4-13, for a description of the parental lines used to produce 'CW 75046'. Similar detailed parental line descriptions are provided for the parents of the other three varieties at page 29, line 14 – page 30, line 2 for 'CW 83201'; page 35, lines 8-15 for 'CW 85029'; and page 40, lines 3-12 for 'CW 95026'.

Applicants maintain, however, that the exact genetic, morphological and/or physiological characteristics of the parents are not directly relevant to the claimed invention given that Applicants have demonstrated that the disclosed methods were used to develop four different, distinct *Medicago sativa* alfalfa varieties each derived from a diverse parental background and each possessing the claimed traits. The as-filed specification provides detailed descriptions of the breeding process used to develop each of

the four diverse, exemplary alfalfa varieties. See, for example, page 25, line 14 – page 26, lines 26 (“CW 75046”); page 30, line 3 – page 31, line 25 (“CW 83201”); page 35, line 16 – page 37, line 8 (“CW 85029”); and page 40, line 13 – page 42, line 8 (“CW 95026”).

What is important is that Applicants have provided the necessary direction for one skilled in the alfalfa breeding arts to develop further *Medicago sativa* alfalfa varieties with the claimed characteristics and the Examiner’s rejection is a clear error. Furthermore, one skilled in the art can use the exemplary alfalfa varieties of the present invention to produce additional lines with the claimed traits.

Prior Art Rejection.

Claims 2-4 and 6-19 stand rejected under 35 USC § 102(b) as allegedly being anticipated by or, in the alternative, under 35 USC § 103 as obvious over Cluff *et al.* (US Patent No. 6,143,951). The Examiner asserts that “Cluff *et al.* teach a *Medicago sativa* alfalfa line, WL-C290, that has very fast recovery after harvest and excellent standability under sprinkler irrigation (see column 17, lines 37-38)”. The two lines of text in Cluff *et al.* cited by the Examiner state that WL-C290 has “Very fast recovery after harvest and **excellent standability under sprinkler irrigation**” (emphasis added). As alluded to by the Examiner, Cluff *et al.* provide no experimental data or evidence to support this statement.

Applicants provided the Examiner with a Declaration Under 37 C.F.R. § 1.132 by Dr. Jonathan M. Reich (“the Reich Declaration”), an inventor of the present invention and an officer of the assignor. The Reich Declaration provides experimental data to definitively demonstrate that ‘WL-C290’ “**is susceptible to lodging under sprinkler irrigation**” (line spanning pages 2-3; emphasis added). The data provided in the Reich Declaration definitively showed that improved alfalfa variety ‘CW 95026’ of the instant invention had significantly ($P<0.05$) more resistance to lodging (90% erect stems) than did ‘WL-C290’ (40% erect stems). As discussed in the Reich Declaration this “**susceptible**” rating for ‘WL-C290’ is based on the ‘Standability Expression (Lodging Resistance)’ industry standards as established by the North American Alfalfa Improvement Conference (“NAAIC”). Clearly, this data demonstrates that ‘WL-C290’ does not have “**excellent standability under sprinkler irrigation**” when compared to the improved varieties of the instant invention.

Despite the fact that Cluff *et al.* specifically assert that WL-C290 has “**excellent standability under sprinkler irrigation**” and Applicants provided experimental evidence that the improved varieties of the instant invention have far superior standability under exactly the same growing conditions, the Examiner summarily dismisses this convincing evidence by merely stating “Applicant is arguing limitations, namely lodging under sprinkler irrigation, that are not in the claims” (Detailed Action, page 11, third paragraph). General statements such as “the evidence is not commensurate with the scope of the

claims" without an explanation supporting such findings are insufficient. See, for example, M.P.E.P. § 716.01(a).

Applicants provided evidence to refute the assertions of the cited reference wherein such evidence was exactly on point to the teaching of the cited reference (i.e., lodging under irrigation conditions). One suspects that if Applicants had provided experimental evidence from non-irrigated plots that the Examiner would have stated that this evidence was not commensurate with the teachings applied. Applicants provided the evidence they did to forestall that very conclusion by the Examiner but still the Examiner did not accept it as convincing.

The specification itself teaches that the "improved standability of the alfalfa plants of the instant invention is even more useful when weather conditions are such that presently-available alfalfa varieties would typically lodge" (page 10, lines 18-20). Irrigation is one such "weather condition" and Applicants have demonstrated that the cited prior art fails to anticipate or even render obvious the instant claimed invention. Actually, the prior art relied upon by the Examiner strongly supports the patentability of the instant claimed invention! Applicants have demonstrated "that the differences in results are in fact unexpected and unobvious and of both statistical and practical significance" when considered in view of the cited prior art. *Ex parte Gelles*, 22 USPQ2d 1318, 1319 (Bd. Pat. App. & Inter. 1992; M.P.E.P. § 716.02(b)). The Examiner has made a clear error by discounting the experimental evidence provided in the Reich Declaration filed with the last response.

SUMMARY

The panel is respectfully to reconsider the pending rejections and to find Applicants' claims allowable based on their originally filed specification, previously filed responses, and this pre-appeal brief request for review and to recognize that the pending claims are allowable.

The Commissioner is hereby authorized to charge any appropriate fees under 37 C.F.R. §§ 1.16, 1.17 and 1.21 that may be required by this paper, and to credit any overpayment, to Deposit Account No. 50-1283.

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